CONGENITAL ZIKA SYNDROME IN INFANTS ≤ 12 MONTHS OF AGE IN THE UK & ROI
(Short Study Name: Congenital Zika Syndrome)

Abstract
Microcephaly and neurological abnormalities in neonates can have multiple causes, one of them being congenital infections. These conditions can have significant consequences for the baby’s future development.

Microcephaly itself is a rare condition, but in Brazil over the last year many more cases of microcephaly and other abnormalities of the brain have been seen than would be expected. There is significant concern from healthcare professionals across the world that this rise is due to increased rates of infection with the Zika virus in women during pregnancy over the same time period. Zika virus infections have been reported from Brazil since early 2015 and since then, the virus has spread and many more countries and territories are now reporting infections worldwide.

Every year a large number of UK residents travel to countries that have been recently affected by Zika. Pregnant travellers are at risk of acquiring Zika virus infection which may then affect their unborn baby. This study aims to identify all babies with microcephaly or neurological abnormalities born in the UK and Ireland, of mothers who have travelled to countries with active Zika transmission.

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Website
www.rcpch.ac.uk/bpsu/ZIKA

Background
Recently, an unusually high number of babies with microcephaly and other abnormalities of the brain were reported in Brazil and declared a Public Health Emergency of International Concern by the WHO in February 2016. These cases coincide with the spread of Zika virus infection 6 months earlier in the same regions of the country. ZIKV infection is in general a mild disease and does not usually require treatment. It is transmitted through the bite of mosquitoes.

In a number of these infants with microcephaly and abnormalities of the brain in Brazil, Zika virus has been detected. Even though not scientifically proven yet, there is strong epidemiological evidence that a significant proportion of the recently reported cases with abnormalities occurred because their mothers were infected with Zika during pregnancy. Since autumn 2015, 42 countries worldwide have reported cases of Zika virus infections. An increase in cases with malformations of the brain has also been reported in French Polynesia, where an outbreak of Zika virus occurred previously.
So far, two babies whose mothers were resident in countries with no active Zika transmission but with a travel history to Brazil during pregnancy, microcephaly and abnormalities of the brain have been reported and Zika virus infection was subsequently confirmed by laboratory tests. On average almost 1.4 million UK residents travel to South and Central America and the Caribbean each year, 25% of those are women of child bearing age who, if pregnant, are at risk of being infected with the Zika virus and of transmitting it to their unborn baby.

Coverage United Kingdom and the Republic of Ireland
Duration April 2016 to April 2018 (25 months of surveillance) with a 12 month follow-up.
Research Questions
- Establish how many babies are born in the UK with microcephaly or neurological abnormalities requiring investigation whose mothers have travelled to a country with active Zika transmission and in how many of those can the presence of Zika virus be confirmed by laboratory methods.
- Describe differences in abnormalities in infants depending on time of exposure to the virus in utero and to compare features of the detected cases with any newly arising evidence on features typical for congenital Zika infection.
- Compare the distribution of cases according to timing of travel in relation to estimated date of delivery (EDD) or last menstrual period (LMP).
Case definition All infants ≤ 12 months of age with a head circumference > 2 standard deviations below the mean for gestational age and sex (i.e. below the 2nd centile) or any neurological abnormality requiring investigation whose mother has travelled to a country with active Zika transmission during pregnancy or in the three months prior to conception.
Exclusion Criteria:
Travel only to countries without reported Zika transmission (Please check on: http://ecdc.europa.eu/en/healthtopics/zika_virus_infection/zika-outbreak/Pages/Zika-transmission-past-9-months.aspx)
Reporting instructions Please report any cases of infant ≤ 12 months in the past month presenting with congenital Zika syndrome as defined by the case definition.
Methods Each paediatrician reporting a child who meets the above case definition of congenital Zika syndrome will be sent a clinical questionnaire by the study team. A second questionnaire will be sent 12 months later to collect follow-up data.
Throughout the study, all patient data will be dealt with in strict confidence, and affected children and their families will not be contacted directly by the Zika study team at any stage.
Funding This study is being funded through Public Health England
Ethics approval Public Health England has approval under Section 251 of the NHS Act 2006 to process confidential patient information for public health purposes. See The Health Service (Control of Patient Information) Regulations 2002.
Support group Microcephaly Support Group

For further information about the study, please contact:
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